EXHIBIT 13

To Plaintiffs' Memorandum Re Relevancy and Discoverability of FDA Inspection and Warning Letter and Recovery Cone Removal System

K032426

OCT 31 2003

510(k) SUMMARY

Submitted By: Cook Incorporated
Contact: Jennifer Bosley, MBA
Regulatory Affairs Coordinator
Tel: (812) 339-2235
Fax: (812) 332-0281

Date Prepared: October 31, 2003

Device:

Trade Name:	Günther Tulip™ Vena Cava Filter and Retrieval Set
Common/Usual Name	Inferior Vena Cava Filter and Retrieval Set
Proposed Classification: & Product Code	Filter, Intravascular, Cardiovascular 21 CFR §870.3375, Class II, DTK—Cardiovascular

Intended Use:

Filter Set:

The Günther Tulip™ Vena Cava Filter Set is indicated for the prevention of recurrent pulmonary embolism via placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulant therapy is contraindicated;
- Failure of anticoagulant therapy in thromboembolic diseases;
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced; and
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The Günther Tulip™ Vena Cava Filter may be retrieved according to the instructions supplied in the section labeled: Optional Retrieval Procedure.

Retrieval Set:

The Günther Tulip™ Vena Cava Filter Retrieval Set has been designed for retrieval of an implanted Günther Tulip™ Vena Cava Filter in patients who no longer require a filter. Retrieval of the filter can be performed only by jugular approach.

Predicate Devices:

The subject devices are substantially equivalent to predicate devices: Günther Tulip™ Vena Cava MR*eye*® Filter, #K000855 (Cook Incorporated); Amplatz Goose Neck Snare, #K972511 (Microvena Corp.); and the Radius Microsnare, #K022201 (Radius Medical Technologies).

EXHIBIT NO. 174
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K032426

Device Description:
The Günther Tulip™ Vena Cava Filter and Retrieval Set is an inferior vena cava filter with a radiopaque band at the tip, which can be introduced via either femoral or jugular vein. The radiopaque retrieval catheter has a braided platinum loop at the distal end.

Substantial Equivalence:
The subject device is similar with respect to intended use, materials and functional characteristics of commercially available predicate devices in terms of section 510(k) substantial equivalence; any differences that may exist do not significantly affect the safety and effectiveness of the device.

Test Data:
The Günther Tulip™ Vena Cava Filter and Retrieval Set have been subjected to and have passed the following tests to ensure reliable design and performance under the specified testing parameters:

Filter Set:
- Biocompatibility
- Material and stress analysis tests
- Clinical experience

Retrieval Set:
- Biocompatibility
- Tensile
- Clinical evaluation

Clinical Experience:
To evaluate the safety of retrieving the Günther Tulip™ Vena Cava Filter, a clinical study was conducted in which 41 patients [female (n=19); male (n=22)] were enrolled for possible retrieval of the filter. Indications for placement of retrievable filter in the study included: bleeding while anticoagulated (n=2), recent bleeding not anticoagulated (n=0), prophylactic pre-op (n=12), prophylactic post-op (n=3), failure of anticoagulation resulting in recurrent PE (n=1), failure of anticoagulation resulting in extension of DVT (n=0), prophylaxis following PE (n=3), prophylaxis with extensive DVT (n=3), trauma (n=13) and other (n=4).

Retrieval was not attempted in 15 patients due to the continued need for permanent implantation of the filter. A total of 26 attempted retrievals in 26 patients were successful. [n= number of filters retrieved] Retrieval of filter immediately after deployment at Day 0 (n=1), Day 2 (n=1), Day 7 (n=1), Day 9 (n=3), Day 10 (n=6), Day 11(n=2), Day 12 (n=1), Day 13 (n=4), Day 14 (n=6), Day 20 (n=1). No adverse events were reported in the retrieved filter group. 23 patients in whom a filter was retrieved were followed for three months post retrieval with no abnormalities reported. Results from the clinical study showed that the filter could be safely retrieved up to 14 days or longer in patients who no longer required an inferior vena cava filter. Time to retrieval ranged from 2-20 days with a mean implantation time of 11.4 days.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 3 1 2003

Cook Incorporated
c/o Ms. Jennifer J. Bosley
Regulatory Affairs Coordinator
P.O. Box 489
Bloomington, IN 47402-0489

Re: K032426
Günther Tulip™ Vena Cava MR*eye*® Filter and Retrieval Set
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular intravascular filter
Regulatory Class: Class II
Product Code: DTK
Dated: August 5, 2003
Received: August 6, 2003

Dear Ms. Bosley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Ashley B. Boam

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K032426

Device Name: Günther Tulip™ Vena Cava Filter and Retrieval Set

Filter Set

The Günther Tulip™ Vena Cava Filter Set is indicated for the prevention of recurrent pulmonary embolism via placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulant therapy is contraindicated;
- Failure of anticoagulant therapy in thromboembolic diseases;
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced; and
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The Günther Tulip™ Vena Cava Filter may be retrieved according to the instructions supplied in the section labeled: Optional Retrieval Procedure.

Retrieval Set

The Günther Tulip™ Vena Cava Filter Retrieval Set has been designed for retrieval of an implanted Günther Tulip™ Vena Cava Filter in patients who no longer require a filter. Retrieval of the filter can be performed only by jugular approach.

PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Ashley B. Boone
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032426

EXHIBIT 14

To Plaintiffs' Memorandum Re Relevancy and Discoverability of FDA Inspection and Warning Letter and Recovery Cone Removal System

K034050

MAR 2 2 2004

510(k)

Summary of Safety and Effectiveness

Submitter: Donna Marshall
Regulatory Affairs Associate II
Cordis Corporation
7 Powderhorn Drive
Warren, NJ 07059
Telephone: 908-412-3844
Fax 908-412-3915
e-mail address dmarshal@crdus.jnj.com

Date Prepared: December 29, 2003

General Provisions:

Trade Name:	Cordis OptEase™ Vena Cava Filter
Common Name:	Vena Cava Filter and Introduction Kit
Classification Name:	Cardiovascular Intravascular Filter (per 21 CFR 870.3375)
Device-classification:	Class II

Predicate Devices: The subject Cordis OptEase Vena Cava Filter is substantially equivalent to:

- Cordis OptEase Permanent Vena Cava Filter and Introduction Kit (#K023116)
- Cordis TrapEase Permanent Vena Cava Filter and Introduction Kit (#K000062 and #K020316)
- Recovery Filter System, Bard Peripheral Vascular, C.R. Bard, Inc. (#K031328)
- Günther Tulip™ Vena Cava Filter and Retrieval set, Cook Incorporated (#K032426)
- Cordis VISTA BRITE TIP® Guiding Catheter (#K965211)

Performance Standards

As per 21 CFR 870.3375, the following special controls were established for cardiovascular intravascular filters:

- Use of International Standards Organization's ISO-10993 'Biological Evaluation of Medical Devices Part I: Evaluation and Testing,
- FDA's Updated 510(k) Sterility Review Guidance (K90-1); Final Guidance for Industry and FDA, August 30, 2002, and
- FDA's Guidance for Cardiovascular Intravascular Filter 510(k) Submissions, dated November 26, 1999.

Indications for Use for Filter:

The Cordis OptEase Vena Cava Filter is indicated for the prevention of recurrent pulmonary embolism via percutaneous placement in the inferior vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated,
- Failure of anticoagulant therapy in thromboembolic diseases,
- Emergency treatment following massive pulmonary embolism where anticipated,
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The OptEase Filter may be removed according to the instructions supplied in the Section labeled: Optional Procedure for Filter Retrieval.

The Angiographic Vessel Dilator is designed to provide angiographic visualization and linear measurement of the vasculature when combined with the delivery of radiopaque contrast media to the Vena Cava.

Indications for Use for Retrieval Catheter:

The Cordis OptEase Retrieval Catheter is indicated for the retrieval of the Cordis OptEase Vena Cava Filter from the inferior vena cava. Retrieval of the OptEase Filter is possible only from the femoral vein approach.

Device Description

The subject OptEase Filter is identical to the predicate OptEase Permanent Vena Cava Filter with the exception of the addition of the retrievability option to the labeling. The OptEase Vena Cava Filter is packaged with a filter introduction kit that includes the Angiographic Vessel Dilator, a directional filter storage tube, catheter sheath introducer and obturator for safe and accurate deployment of the filter.

The subject OptEase Filter is substantially equivalent to the predicate devices (i.e., OptEase Permanent Vena Cava Filter, TrapEase Permanent Vena Cava Filter, Recovery Filter System, and Günther Tulip™ Vena Cava Filter and Retrieval Set).

Device Description (continued)

The subject OptEase Retrieval Catheter is an 80 cm long, 10F catheter with radiopaque tip. The subject device is packaged separately and is intended for the percutaneous retrieval of the OptEase Filter from the inferior vena cava when used with an appropriate Endovascular snare. The subject device is substantially equivalent to the predicates devices (i.e., the Günther Tulip™ Vena Cava Filter and Retrieval Set and the VISTA BRITE TIP® Guiding Catheter).

Performance Data:

The safety and effectiveness of the Cordis OptEase Vena Cava Filter and the OptEase Retrieval Catheter have been demonstrated via data collected from *in-vitro*, animal and clinical testing and analyses. The safety of retrieval of the OptEase Filter was evaluated in a prospective clinical study (n = 21 retrieval patients) and in a retrospective clinical experience (n = 40 retrieval patients). In the prospective clinical study, the time to retrieval ranged from 5 – 14 days (mean implantation time of 11.1 ± 1.8 days). In the retrospective clinical experience, the time to retrieval ranged from 3 – 48 days in 29 patients (mean implantation time of 16.4 ± 7.2 days). Eleven patients in the retrospective clinical experience had their filter captured from the vessel wall and then redeployed at the different location within the inferior vena cava (capture time ranged from 4 – 30 days, mean of 13.8 ± 6.1 days). The OptEase Filter was subsequently retrieved from this subset of patients.

Summary of Substantial Equivalence

The design, material, components, and fundamental technology featured with the Cordis OptEase Vena Cava are substantially equivalent to those featured with the predecessor Cordis OptEase Permanent Vena Cava Filter and Introduction Kit and the Cordis TrapEase Permanent Vena Cava Filter and Introduction Kit. In addition, the intended use for the OptEase Vena Cava Filter is substantially equivalent with the Recovery Filter System and the Günther Tulip Vena Cava Filter and Retrieval Set.

The design and materials of the OptEase Retrieval Catheter are substantially equivalent to the VISTA BRITE TIP Guiding Catheter. The intended use for OptEase Retrieval Catheter is substantially equivalent to the Günther Tulip Vena Cava Filter and Retrieval Set.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2004

Cordis Corporation
c/o Ms. Donna Marshall
Regulatory Affairs Associate II
7 Powder Horn Drive
Warren, NJ 07059

Re: K034050
Trade Name: Cordis OptEase™ Vena Cava Filter and Optease ™ Retrievable Catheter
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: II (two)
Product Code: DTK
Dated: December 29, 2003
Received: December 30, 2003

Dear Ms. Marshall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Lo Duca

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K034050

Device Name: Cordis OptEase™ Vena Cava Filter and OptEase™ Retrieval Catheter

Indications For Use:

The **OPTEASE** Filter is indicated for use in the prevention of recurrent pulmonary embolism (PE) via percutaneous placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated,
- Failure of anticoagulant therapy for thromboembolic disease,
- Emergency treatment following massive pulmonary embolism where anticipated,
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed, or is contraindicated

The **OPTEASE** Filter may be retrieved according to the instructions supplied in the Section labeled: **Optional Procedure for Filter Retrieval.**

The Angiographic Vessel Dilator is designed to provide angiographic visualization and linear measurement of the vasculature when combined with the delivery of radiopaque contrast media to the vena cava.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Volkmer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K034050

EXHIBIT 15

To Plaintiffs' Memorandum Re Relevancy and Discoverability of FDA Inspection and Warning Letter and Recovery Cone Removal System

(FILED UNDER SEAL)

EXHIBIT 16

To Plaintiffs' Memorandum Re Relevancy and Discoverability of FDA Inspection and Warning Letter and Recovery Cone Removal System

Robert W. Boatman (009619) - rwb@gknet.com
Paul L. Stoller (016773) - paul.stoller@gknet.com
Shannon L. Clark (019708) - SLC@gknet.com
GALLAGHER & KENNEDY, P.A.
2575 East Camelback Road
Phoenix, Arizona 85016-9225
Telephone: (602) 530-8000

Ramon Rossi Lopez (CA Bar No. 86361)
(admitted *pro hac vice*)
LOPEZ McHUGH LLP
100 Bayview Circle, Suite 5600
Newport Beach, California 92660
rlopez@lopezmchugh.com

Co-Lead/Liaison Counsel for Plaintiffs

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	MD No. 02641 **PLAINTIFFS' NOTICE OF DEPOSITION PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 30(b)(6) and RELATED REQUESTS FOR PRODUCTION OF DOCUMENTS**

Gallagher & Kennedy, P.A.
2575 East Camelback Road
Phoenix, Arizona 85016-9225
(602) 530-8000

YOU ARE HEREBY NOTIFIED that, in accordance with Rule 30(b)(6), Fed. R. Civ. P., Plaintiff will depose the representative of C R Bard Incorporated and Bard Peripheral Vascular Incorporated ("BARD") who is the most knowledgeable regarding the following matters set forth in Exhibit A.

DATE/TIME OF DEPOSITION: December 15, 2015, 10 a.m.

LOCATION OF DEPOSITION: Gallagher & Kennedy, P.A.
2575 East Camelback Road, Suite 1100
Phoenix, Arizona 85016

The deposition will be taken upon oral examination before a stenographic court reporter or some other officer duly authorized by law to take oaths and acknowledgements in the State of Arizona. The deposition will continue day to day until completed and will be videotaped. This deposition is being taken for the purpose of discovery, for use at trial or both of the foregoing, or for such other purposes as permitted under the applicable rules and governing law.

PLEASE TAKE FURTHER NOTICE that, pursuant to Rule 34, Fed. R. Civ. P., BARD is to produce by November 10, 2015 the documents and tangible things identified in Exhibit B attached hereto.

DATED this 5th day of November 2015.

GALLAGHER & KENNEDY, P.A.

By: _____

Robert W. Boatman
Paul L. Stoller
Shannon L. Clark
2575 East Camelback Road
Phoenix, Arizona 85016-9225

LOPEZ McHUGH LLP
Ramon Rossi Lopez (CA Bar No. 86361)
(admitted *pro hac vice*)
100 Bayview Circle, Suite 5600
Newport Beach, California 92660

Co-Lead/Liaison Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on November 5th, 2015 a true and correct copy of the foregoing was sent via U.S. Mail and/or Electronic Mail to:

James R. Condo
Snell & Wilmer LLP
One Arizona Center
400 East Van Buren Street
Suite 1900
Phoenix, Arizona 85004
Attorneys for Defendants

Richard B. North, Jr.
Nelson Mullins Riley & Scarborough LLP
Atlantic Station
201 17th Street NW, Suite 1700
Atlanta, Georgia 30363
Attorneys for Defendants

*Counsel for Plaintiffs will be served in accordance with the Court's Case Management Order No. 1

EXHIBIT A

Definitions

The following definitions apply to this Notice of Deposition, including those matters set forth in Exhibit A hereto, and are deemed to be incorporated into each subject and request for documents listed below:

1. "Identify" or "identity" with respect to persons, means to give, to the extent known, the person's full name, present or last known address, and when referring to a natural person, additionally, the present or last known place of employment.

2. BARD means defendants C.R. BARD INC. and BARD PERIPHERAL VASCULAR. INC., and any of its subsidiaries, affiliates, officers, agents, attorneys, employees, representatives, or others acting on its behalf.

3. "Person" means natural person, as well as corporate and/or governmental entity.

4. "IVC Filter" means all IVC Filters manufactured or distributed by BARD or its predecessors prior to assignment or sale of such filters to BARD. Also included is any device intended to retrieve any filter or to introduce any filter into the body.

5. "Relating to," "relate to," "referring to," "refer to," "reflecting," "reflect," "with regard to," "concerning," or "concern" shall mean evidencing, regarding, concerning, discussing, embodying, describing, summarizing, containing, constituting, showing, mentioning, reflecting, pertaining to, dealing with, relating to, referring to in any way or manner, or in any way logically or factually, connecting with the matter described in that paragraph of these demands, including documents attached to or used in the preparation of or concerning the preparation of the documents.

6. "Documents" as used in this Request is coextensive with the meaning of the terms "documents" and "tangible things" in FRCP 34, and shall have the broadest possible meaning and interpretation ascribed to the terms "documents" and "tangible things" under FRCP 34. Consistent with the above definition, the term document shall include, without limitation, any written, printed, typed, photostatic, photographed,

recorded, computer-generated, computer- stored, or otherwise maintained or reproduced communication or representation, any data compilation in any form, whether comprised of letters, words, numbers, pictures, sounds, bytes, e-mails, electronic signals or impulses, electronic data, active files, deleted files, file fragments, or any combination thereof including, without limitation, all memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, projections, estimates, working papers, accounts, analytical records, reports and/or summaries of investigations, opinions or reports of consultants, opinions or reports of experts, opinions or reports of accountants, other reports, trade letters, press releases, comparisons, books, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, forecasts, drawings, diagrams, instructions, minutes of meetings or communications of any type, including inter- and intra-office communications, questionnaires, surveys, charts, graphs, photographs, phonographs, films, tapes, discs, data cells, drums, printouts, all other compiled data which can be obtained (translated, if necessary, through intermediary or other devices into usable forms), documents maintained on, stored in or generated on any electronic transfer or storage system, any preliminary versions, drafts or revisions of any of the foregoing, and other writings or documents of whatever description or kind, whether produced or authorized by or on behalf of you or anyone else, and shall include all non-identical copies and drafts of any of the foregoing now in the possession, custody or control of you, or the former or present directors, officers, counsel, agents, employees, partners, consultants, principals, and/or persons acting on your behalf.

7. "Or" and "and" will be used interchangeably.

Deposition Subject Matter

Pursuant to Rule 30(b)(6), BARD shall designate and produce for deposition one or more of its officers, directors, managing agents, or other persons who consent to testify on its behalf concerning the following subject matters:

///

///

FDA WARNING LETTER DATED JULY 13, 2015:

1. All communications with FDA officials regarding the subject matter and content of the warning letter issued by FDA on July 13, 2015 including but not limited to communications described in the letter.

2. The identity of BARD's corporate officers and other employees (including but not limited to their titles, duties and dates of such responsibility) who were and are responsible for communicating with regulatory officials with the FDA and related regulatory bodies concerning the subject matter and content of the warning letter issued by FDA on July 13, 2015.

3. The visits/inspections from/by the FDA to Bard facilities on the dates listed in the warning letter issued by the FDA on July 13, 2015.

4. The failure to establish and maintain procedures for receiving, reviewing and evaluating complaints associated with Bard's IVC filters and Bard IVC filter removal products as described in the warning letter issued by the FDA on July 13, 2015.

5. Determination of lot numbers subject to the failure to establish and maintain procedures for acceptance of incoming product as described in paragraph 5 of the warning letter issued by the FDA on July 13, 2015.

6. The failure to submit reports as described in paragraph 7 of the warning letter issued by the FDA on July 13, 2015 and the responses submitted by Bard to the FDA listed as inadequate.

7. Actions taken by defendants since the issuance of the warning letter issued by FDA on July 13, 2015.

EXHIBIT B

DOCUMENTS TO BE PRODUCED

1. An unredacted and final copy of the warning letter issued by FDA on July 13, 2015 to Bard.

2. All communications with FDA related to the subject matter of the warning letter issued by the FDA on July 13, 2015.

3. All documents which reflect a regulatory log of contacts with the FDA regarding the warning letter issued by FDA on July 13, 2015.

4. All complaint files referenced in the warning letter issued by FDA on July 13, 2015.

5. All complaint files provided to and/or reviewed by FDA as part of the investigation and inspections that resulted in the warning letter issued by FDA on July 13, 2015.

6. All documents and material provided to FDA during the course of its inspection and investigation that resulted in the warning letter issued by FDA on July 13, 2015.

7. All internal communications relating to the subject matter of the warning letter issued by FDA on July 13, 2015.

8. Communications with FDA and internally at BARD since the issuance of the warning letter issued by FDA on July 13, 2015 which pertain to the subject matter and content of said warning letter.

9. Documents reflecting actions taken by defendants as a result of the warning letter issued by FDA on July 13, 2015.

10. Observations noted on FDA Forms 483, Lists of Inspectional Observations that were issued to you at the close of the FDA's inspections that are referenced in the warning letter issued by FDA on July 13, 2015.

EXHIBIT 17

To Plaintiffs' Memorandum Re Relevancy and Discoverability of FDA Inspection and Warning Letter and Recovery Cone Removal System

Robert W. Boatman (009619) - rwb@gknet.com
Paul L. Stoller (016773) - paul.stoller@gknet.com
Shannon L. Clark (019708) - SLC@gknet.com
GALLAGHER & KENNEDY, P.A.
2575 East Camelback Road
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Telephone: (602) 530-8000

Ramon Rossi Lopez (CA Bar No. 86361)
(admitted *pro hac vice*)
LOPEZ McHUGH LLP
100 Bayview Circle, Suite 5600
Newport Beach, California 92660
rlopez@lopezmchugh.com

Co-Lead/Liaison Counsel for Plaintiffs

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	MD No. 02641 **PLAINTIFFS' SECOND SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS**

Plaintiffs, by and through undersigned counsel and pursuant to Fed. R. Civ. P. 34, hereby request that Defendants CR Bard Incorporated and Bard Peripheral Vascular Incorporated produce the documents identified in the following Requests for Production of Documents within thirty (30) days of this Request. Production shall be made at the offices of Gallagher & Kennedy, P.A., 2575 East Camelback Road, Phoenix, Arizona 85016.

INSTRUCTIONS FOR REQUESTS FOR PRODUCTION

1. The response to each Request shall include all documents within your possession, custody, or control, including, but not limited to, documents in the possession, custody, or control of your investigators, consultants, attorneys, or other agents. Any reference to "you" shall include your consultants, attorneys, or other agents.

2. As used herein, the term "document" means all written, recorded, and graphic and electronically stored matter of every type and description encompassed by

Fed. R. Civ. P. 34(a)(1), including, but not limited to, writings, graphs, charts, photographs, sound recordings, images, drawings, notes, contracts, agreements, correspondence, letters, memoranda, appointment books, calendars, all forms of communication (including physical documents, e-mail, instant messaging, texts, tweets, social-media postings and communications), and all electronically stored information in any medium from which information can be obtained either directly or, if necessary, after translation by the responding party into a reasonably usable form.

3. You shall produce any and all documents responsive to each Request unless an objection is stated to a Request. If you object to all or any part of a Request, you shall state the reasons for the objection. If objection is made to part of an item or category, the part shall be specified. If you object to only part of an item or category, you shall produce any and all documents responsive to the part or parts of the item or category to which you do not object.

4. If you contend that an identified document would be excludable from production, state the reasons for such objection or grounds for exclusion and identify each person having knowledge of the factual basis, if any, on which the privilege or other ground is asserted.

5. You should produce documents for inspection as they are kept in the usual course of business or, alternatively, organize and label them to correspond with the categories in the request.

6. Production of Electronically Stored Information (ESI).

a. Production of Native Form. ESI should be produced in native form with all metadata intact unless such form would not be reasonably usable by third parties (such as ESI from legacy or proprietary systems).

b. Production in Non-Native Form for ESI not Reasonably Usable. If ESI would not be reasonably usable by third parties, it should be produced as follows:

Conversion to TIFF. ESI should be converted into *.tif image format with single-page files at 300 DPI, Group IV compression, with original orientation maintained. All available fielded metadata and text-searchable information shall be extracted from the native document and produced with the ESI as part of the document. Any bates labeling on the *.tif images should be done in a consistent font and should not obscure any visible text, image, or portion of the original file.

Extracted Full Text. The producing party should produce the full extracted text in the form of a single *.txt file for each non-native file. The text file name shall correspond to the bates label of the associated document.

Production of Metadata. The producing party should provide the following metadata (as applicable by file type) for all ESI: begdoc, enddoc, begattach, endattach, custodians, recordtype, doctype, emailsubject, docauthor, to, cc, bcc, docdate, parentdate, datesent, timesent, datercvd, timercvd, datelastmod, timelastmod, datelastprint, timelastprint, filename, title, attachname, docext, filesize, md5hash, numattach, pgcount, nativefile, textfile, organization, comments, lastauthor, revision, and locations.

Production of Load File. For all Non-native productions, the producing party should produce an appropriate data load file in Concordance (.dat) format (DAT files should be produced in UTF8) and image load file in Opticon (.opt) format.

Preservation of Document Relationships. In the production of TIFF format images, the producing party should preserve all relationships, such as parent-child, between documents by producing relating documents sequentially. For parent documents with

attachments (or exhibits), the attachments should be produced as independent files immediately following the main/parent document. Likewise, embedded files should be produced as separate files as attachments to the file in which they were embedded.

c. ESI with Links to other ESI or Database(s). For any ESI files that contain links to other documents, files, ESI, web addresses, or to database information, the producing party should ensure that the relationship between the files is preserved and that such links remain active. Where the form of production precludes the ability to have active links, the producing party should produce copies of the linked documents, files, ESI, or web addresses as related documents. If produced ESI includes a link to a database or information in a database, the producing party should provide reasonable access to the database or to the database information in such a way that Plaintiffs can reasonably access or determine the linked information.

d. ESI requiring Proprietary Software. If proprietary software unavailable to Plaintiffs is required to review the producing party's ESI in native form, the producing party should provide reasonable access to the proprietary software for purposes of review of ESI by Plaintiffs or their representatives.

7. For each document requested which you are unable to produce and which was at any time in your possession, custody or control or which you had access to, specify in detail:

a. The nature and author of the document;

b. All recipients of the document and any copies thereof;

c. A summary of the information contained in the document;

d. The date and manner in which you lost possession, custody or control of the document;

e. Identify all persons who had access to the document while it was within your possession, custody or control; and,

f. Identify all persons who have knowledge of the contents of the document.

DEFINITIONS

1. "Bard" means C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.
2. "BPV" means Bard Peripheral Vascular, Inc.
3. "C.R. Bard" means C.R. Bard, Inc.
4. "FDA" means the federal Food and Drug Administration.
5. "IVC" means inferior vena cava.

REQUEST FOR PRODUCTION

Request for Production No. 9:

Complete complaint files from 1998 to the present for all Bard IVC filter products, including all information related to any IVC filter complaints or adverse events on Bard's Trackwise systems as well as the format of such files that predate the adoption of Trackwise.

Request for Production No. 10:

All internal policies and procedures in place at any time from 2003 to the present relating to:

a. quality assurance,

b. corrective or preventative actions,

c. design controls,

d. design testing,

e. field assurance,

f. post-market surveillance,

g. complaint evaluation, investigation, or handling,

h. risk management,

i. risk evaluation,

j. process for making a determine of malfunction versus serious injury,

k. acceptance of incoming product, and

l. inspection, testing, or other verification of incoming products as conforming to specified requirements.

This request includes all current and former policies and procedures relating to the foregoing subjects.

Request for Production No. 11:

All training materials that have been used at any time from 2003 to the present for quality assurance or complaint handling, including but not limited to materials in the form of procedures, standard operating procedures, forms, work instructions, training logs, training requirements, and testing or quizzes

Request for Production No. 12:

All documents that evince, relate, or refer to communications with King & Spalding regarding Bard's response to the FDA's inspections of Bard facilities in October 2014 through January 2015 and the FDA's findings of violations, including the FDA's issuance of Form FDA-483s to C.R. Bard and BPV, dated respectively November 25, 2014 and January 5, 2015, and the "Warning Letter" to C.R. Bard, dated July 13, 2015, including but not limited to any and all drafts of communications to the FDA, emails or other communications relating to such drafts, as well as final communications in any form to the FDA.

Request for Production No. 13:

All documents that evince, relate, or refer to communications with Hogan Lovells regarding Bard's response to the FDA's inspections of Bard facilities in October 2014 through January 2015 and the FDA's findings of violations, including the FDA's issuance

of Form FDA-483s to C.R. Bard and BPV, dated respectively November 25, 2014 and January 5, 2015, and the "Warning Letter" to C.R. Bard, dated July 13, 2015, including but not limited to any and all drafts of communications to the FDA, emails or other communications relating to such drafts, as well as final communications in any form to the FDA.

Request for Production No. 14:

All documents that evince, relate, or refer to any communications by King & Spalding on behalf of Bard with the FDA regarding Bard's response to the FDA's inspections of Bard facilities in October 2014 through January 2015 and the FDA's findings of violations, including the FDA's issuance of Form FDA-483s to C.R. Bard and BPV, dated respectively November 25, 2014 and January 5, 2015, and the "Warning Letter" to C.R. Bard, dated July 13, 2015.

Request for Production No. 15:

All documents that evince, relate, or refer to any communications by Hogan Lovells on behalf of Bard with the FDA regarding Bard's response to the FDA's inspections of Bard facilities in October 2014 through January 2015 and the FDA's findings of violations, including the FDA's issuance of Form FDA-483s to C.R. Bard and BPV, dated respectively November 25, 2014 and January 5, 2015, and the "Warning Letter" to C.R. Bard, dated July 13, 2015.

Request for Production No. 16:

All documents, files, or drafts that relate to the monthly reports provided to the FDA by Bard in 2015 relating to the FDA's inspections of Bard facilities in October 2014 through January 2015 and the FDA's findings of violations, including the FDA's issuance of Form FDA-483s to C.R. Bard and BPV, dated respectively November 25, 2014 and January 5, 2015, and the "Warning Letter" to C.R. Bard, dated July 13, 2015, including

but not limited to the native files of the "periodic updates" to the FDA on which Chad Modra worked with King & Spalding or Hogan Lovells.

Request for Production No. 17:

The documents that reflect the personnel at King & Spalding in addition to Mr. Niedelmann who worked with Chad Modra in responding to the FDA arising out of the FDA's inspections of Bard facilities in October 2014 through January 2015 and the FDA's findings of violations, including the FDA's issuance of Form FDA-483s to C.R. Bard and BPV, dated respectively November 25, 2014 and January 5, 2015, and the "Warning Letter" to C.R. Bard, dated July 13, 2015.

Request for Production No. 18:

All files for or communications with Dr. Shane Gad and/or Dr. Scott Terratola, relating to the FDA's inspections of Bard facilities in October 2014 through January 2015 and the FDA's findings of violations, including the FDA's issuance of Form FDA-483s to C.R. Bard and BPV, dated respectively November 25, 2014 and January 5, 2015, and the "Warning Letter" to C.R. Bard, dated July 13, 2015, or Bard's responses thereto.

Request for Production No. 19:

All communications with Dr. Shane Gad regarding IVC filter issues, including but not limited to any analysis or reports by or from Dr. Gad regarding IVC filters.

Request for Production No. 20:

All communications with Dr. Scott Terratola regarding IVC filter efficacy, safety, or performance, including but not limited to any analysis or reports by or from Dr. Terratola regarding IVC filters.

Request for Production No. 21:

All internal information and reports by Bard regarding tracking, trending, or analysis with respect to any and all Bard IVC filters from 2003 through the present, including but not limited to:

a. modes of failure,

b. impact on patients,

c. patient outcomes,

d. the types or severity of events,

e. failure, severity, or event codes,

f. FDA codes, and/or

g. the nature of events.

This request includes any and all reports generated on routine or irregular bases

Request for Production No. 22:

All documents relating to any and all annual internal audits of Bard's quality systems from 2003 through the present.

Request for Production No. 23:

All documents relating to any and all external audits of Bard's systems, processes, devices, or files that include files relating to IVC filters, its quality systems, or its complaint files.

Request for Production No. 24:

All Failure Mode Effect Analyses (FMEAs) for Bard IVC filters from 2003 through the present.

Request for Production No. 25:

All clinical severity checklists relating to IVC filters that have been in effect from any time from 2003 through the present.

Request for Production No. 26:

The complete employment files at Bard for:

a. Chad Modra,

b. Maureen Uebelocker,

c. John Wheeler, and

d. Judy Ludwig.

Request for Production No. 27:

All job descriptions for the positions held by Chad Modra, Maureen Uebelocker, John Wheeler, and Judy Ludwig in 2014 and 2015.

Request for Production No. 28:

All information packets, agendas and "output action items" for the meetings of the "management board" responsible for the management review process.

Request for Production No. 29:

Chad Modra's file of notes and related materials for the meetings or actions of the "management board" responsible for the management review process.

Request for Production No. 30:

The notes or files of any other Bard employee relating to the meetings or actions of the "management board" responsible for the management review process.

Request for Production No. 31:

All documents that reflect or embody or have as any part of their subject matter the management board's guidelines or rules regarding injury frequency or severity for any Bard IVC filters.

Request for Production No. 32:

All documents relating to any and all Corrective and Preventative Actions (CAPA) relating to any Bard IVC filter.

Request for Production No. 33:

Any and all documents that demonstrate communications from the FDA regarding whether the failure of an IVC filter to deploy is a reportable event to the FDA, including but not limited to any correspondence from the FDA to Bard's medical director and any "meeting minutes" as testified to by Chad Modra.

Request for Production No. 34:

All documents that evince, relate, or refer to FDA guidance given to Bard regarding the classification of events for purposes of reporting adverse events to the FDA, including but not limited to all communications and correspondence with the FDA as well as internal Bard communications such as memoranda, emails, notes, and agendas.

Request for Production No. 35:

All internal communications (including all emails) of Bard employees and agents regarding the FDA's inspections of Bard facilities in October 2014 through January 2015 and the FDA's findings of violations, including the FDA's issuance of Form FDA-483s to C.R. Bard and BPV, dated respectively November 25, 2014 and January 5, 2015, and the "Warning Letter" to C.R. Bard, dated July 13, 2015, or Bard's responses thereto. This request specifically includes but is not limited to all communications regarding the

retrospective review of IVC filter complaint records and the reclassification of reportability status for such records.

DATED this 4th day of January 2016.

GALLAGHER & KENNEDY, P.A.

By: _____

Robert W. Boatman
Paul L. Stoller
Shannon L. Clark
2575 East Camelback Road
Phoenix, Arizona 85016-9225

LOPEZ McHUGH LLP
Ramon Rossi Lopez (CA Bar No. 86361)
(admitted *pro hac vice*)
100 Bayview Circle, Suite 5600
Newport Beach, California 92660

Co-Lead/Liaison Counsel for Plaintiffs

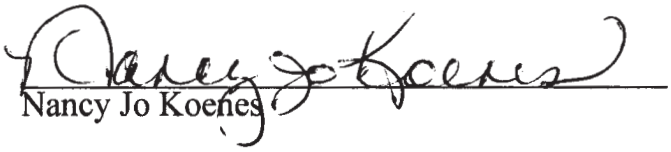
CERTIFICATE OF SERVICE

I hereby certify that on January 4, 2016, a true and correct copy of the foregoing was sent via U.S. Mail and/or Electronic Mail to:

James R. Condo
Snell & Wilmer LLP
One Arizona Center
400 East Van Buren Street
Suite 1900
Phoenix, Arizona 85004
Attorneys for Defendants

Richard B. North, Jr.
Nelson Mullins Riley & Scarborough LLP
Atlantic Station
201 17th Street NW, Suite 1700
Atlanta, Georgia 30363
Attorneys for Defendants

*Counsel for Plaintiffs will be served in accordance with the Court's Case Management Order No. 1



Nancy Jo Koenes

5178716v1/26997-0001

EXHIBIT 18

To Plaintiffs' Memorandum Re Relevancy and Discoverability of FDA Inspection and Warning Letter and Recovery Cone Removal System

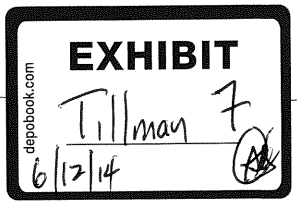
From: Hudnall, Janet [/O=BARD/OU=TPE AG/CN=RECIPIENTS/CN=JHUDNALL]
Date: 7/15/2004 11:24:56 PM
To: TPE-Interventional Sales-DG [/O=BARD/OU=MHL AG/cn=Recipients/cn=TPE-InterventionalSales-DG], Coutanche, Monica [/O=BARD/OU=MHL AG/cn=Recipients/cn=MCoutanche], Lawson, Matthew [/O=BARD/OU=SYD AG/cn=Recipients/cn=MLawson], Ruggiero, Roberto [/O=BARD/OU=ROM AG/cn=Recipients/cn=RRuggiero], Borremans, Frank [/O=BARD/OU=OLN AG/cn=Recipients/cn=FBorremans]
CC: McDermott, John [John.McDermott@crbard.com], Shifrin, Kevin [Kevin.Shifrin@crbard.com], Edwards, Mary [/O=BARD/OU=TPE AG/CN=RECIPIENTS/CN=MEdwards], Uelmen, Doug [Doug.Uelmen@crbard.com], Carr, Robert [Robert.Carr@crbard.com], DeCant, Len [/O=BARD/OU=TPE AG/CN=RECIPIENTS/CN=LDeCant]
Subject: Vena Cava Filter Complications Q&A
Attachments: Vena Cava Filter Complications 3.doc

All,

Attached is a document that details some frequently asked questions regarding Recovery complications. This document contains verbiage that has been corporate-reviewed and approved. Please do not deviate from this script and please do not distribute--this document is strictly for internal use only.

Please feel free to contact me with any questions/concerns.

Regards,
Janet



Vena Cava Filter Complications – FAQs

Q: What is the migration rate for Recovery® Filter?

A: It is difficult to determine actual rates. Acceptable statistical ranges cannot be reliably calculated from available data. However, estimates based on MAUDE and sales data suggest that there is no significant difference in the rates of these complications between competitive devices, including the Recovery® Filter.

The following table shows the number of incidents reported to the MAUDE database for period beginning Q2, 2003 through Q2,2004:

Complication Type	Recovery	Total for All Filters (includes Recovery)
Migration	9	39
Central Migration (Subset of Migration)	7	23
Caval Penetration	1	2
Caval Perforation	0	12
Caval Thrombosis	0	10
PE	4	5
Filter Fracture	1	13
Death	5	16

Reporting period: April 2003 - June 2004

Q: What were the circumstances surrounding the deaths?

A: In all cases of migration-related deaths, the filter was reportedly placed appropriately; however, a massive thrombus burden overwhelmed the filter. The diameter of the thrombus distended the vena cava to the point where its diameter exceeded the physical limits of the filter.

Q: Why did the new complaints not prompt a product hold?

A: The initial hold was an internal action. The FDA was never involved in the decision to put the product on hold. It was a conservative step that allowed us the time to determine if our overall complication rates were comparable to those reported in the literature and the MAUDE database for other IVC filters.

Every reported complication is treated with the utmost care and seriousness. Although the new reported migrations are unfortunate, they still fall within our expected parameters.

Q: Why didn't you tell us about the complications before the MAUDE database update?

A: It is inappropriate to discuss reported complications prior to the completion of the investigation. For each case reported, we conduct a thorough investigation according to our established, systematic process which can take a great deal of time and resources.

Q: Is Recovery® Filter a safe device?

A: The Recovery Filter was rigorously tested for all physical performance characteristics according to our established test methods and protocols and was found to meet all test specifications and requirements.

As stated previously, Recovery® Filter's overall complication rates are comparable to those reported in the literature and the MAUDE database for other IVC filters.

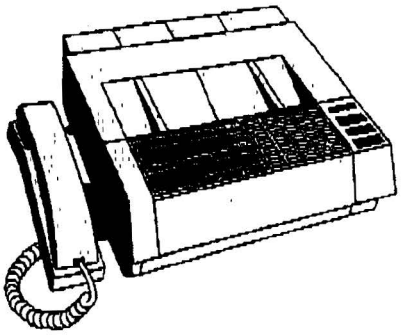
EXHIBIT 19

To Plaintiffs' Memorandum Re Relevancy and Discoverability of FDA Inspection and Warning Letter and Recovery Cone Removal System

(part 1)

C. R. BARD, INC.
730 CENTRAL AVENUE
MURRAY HILL, NJ 07974

Fax# 908-277-8087
Tel # 908-277-8341
E-Mail: paula.pizzi@crbard.com



FAX

TO: **Mary Edwards**

FROM: **Paula Pizzi for Paul Kowalczyk**

DATE: **May 11, 2004**

NUMBER OF PAGES INCLUDING COVER SHEET: 56

If transmission is not complete, please notify sender at (908) 277-8341.

COMMENTS:

Church, Nikki

From: Barry, Brian
Sent: Monday, May 10, 2004 4:05 PM
To: 'Kimberly Ocampo'; Church, Nikki
Cc: Ganser, Christopher; Kowalczyk, Paul
Subject: RE: Latest Bard Filter Plan and Q&As

Kimberly:

Hi, per my discussion with Chris Ganser, this piece will need to go through the standard Bard approval process for external pieces.

To that end, per copy of this email I am forwarding this piece to Nikki Church of our law Department, who coordinates such reviews. Nikki, please log and route per standard procedure.

Thanks

Brian

Brian R. Barry
V.P. Corporate Regulatory & Clinical Affairs
C.R. Bard Inc.
730 Central Avenue
Murray Hill NJ 07974

908-277-8062
908-277-8087 (fax)
908-472-5177 (cell)

-----Original Message-----
From: Kimberly Ocampo [mailto:kocampo@HillandKnowlton.com]
Sent: Monday, May 10, 2004 11:24 AM
To: Barry, Brian
Subject: FW: Latest Bard Filter Plan and Q&As

Hello Brian. Please see below. I'm not sure if I was given the correct spelling of your last name. Thank you.
-----Original Message-----
From: Kimberly Ocampo
Sent: Monday, May 10, 2004 11:19 AM
To: 'brian.berry@crbard.com'
Cc: Lee Lynch; 'Glass, Holly'; 'jlehmann@lehmannthomas.com'; Passero, Donna; 'Hudnall, Janet'; 'john.mcdermott@crbard.com'; 'christopher.ganser@crbard.com'; 'doug.uelmen@crbard.com'
Subject: Latest Bard Filter Plan and Q&As

Dear Brian:

On behalf of the Bard Team currently involved with development of the crisis plan and associated materials in support of the Recovery Filter, please review the attached draft communications plan, internal Q&A and external Q&A. These drafts incorporate the comments from the following: Dr. John Lehmann, Donna Passero, Janet Hudnall, John McDermott, Chris Ganser, Doug Uelmen and Holly Glass.

Could you please provide your edits and comments to Hill & Knowlton (Lee Lynch at llynch@hillandknowlton.com or 571.214.8799 or myself) by close of business, Wednesday, May 12? If you have any questions about these documents, please contact Holly Glass, Lee

or myself.

Once we incorporate your changes, we will distribute the latest drafts to the entire team and schedule a call to discuss further edits next week.

Thank you.

Regards,

Kimberly Ocampo

Kimberly Ocampo
Senior Account Supervisor
Hill & Knowlton Washington, D.C.
p: (202) 944 1905
c: (202) 997 4420
f: (202) 944 1970
kimberly.ocampo@hillandknowlton.com

HILL & KNOWLTON

"Best in International PR -
-- *Thomas L. Harris/Impulse Research*

PRIVILEGED & CONFIDENTIAL

HILL & KNOWLTON

MEMO

To: **Holly Glass, Chris Ganser, Janet Hudnall, Donna Passero and Brian Berry**

From: **Lee Lynch and Kimberly Ocampo**

Date: **May 10, 2004**

Subject: **Recovery Filter Crisis Communications Plan**

This document provides a step-by-step guide for implementing an immediate communications strategy to ensure C.R. Bard is prepared for any news coverage that may result from pending investigations surrounding the Recovery Vena Cava Filter.

The information presented in this plan is privileged and confidential and is for internal use only.

RECOVERY® FILTER CRISIS COMMUNICATIONS PLAN **5/10/04**

OVERVIEW

As with previous crisis plans Hill & Knowlton has prepared for C. R. Bard, this guide will help Bard's Corporate Communications Team prepare for and properly manage controversial or negative stories surrounding the Recovery® Vena Cava Filter.

The proliferation of unfavorable press in top-tier media outlets can cause an onslaught of negative activity: a company's employee morale may suffer, stock prices may plummet, analysts may downgrade the affected company's rating, and longstanding reputations may be ruined temporarily or even permanently. Extensive preparation is critical to help prevent the spread of damaging coverage.

Currently, Bard is investigating the reported migration of the Recovery Vena Cava Filter in two separate incidences.

The first reported incident under investigation took place at ~~Baptist Hospital of Miami~~, ~~FL~~, following bariatric surgery. The coroner's report ~~states~~ that filter migration ~~is~~ the cause of death. Bard ~~is conducting~~ its own investigations to research the validity of this claim and ~~hired Dr. Luke Brennecke of Pathology Associates in Frederick, MD~~ to conduct a subsequent pathological evaluation of the thrombus surrounding the vena cava filter removed during the autopsy.

The ~~summary provided in the CMP12933 PATH Report signed by Dr. Brennecke~~ follows:

The clot formation was an ante mortem event; it had most likely been deposited around the device over a period of a couple of days. The location of the device during clot deposition could not be determined. The bacterial colonizing the clot most likely represents post mortem growth of normal saprophytic bacteria. Because extensive (destructive) sampling of the clot was prohibited (telephonic instructions), no tissue was sampled from around the hooks that were still embedded within the clot. Should they be sampled, it is possible that segments of the mural architecture (IVC or elsewhere) might be present.

It is important to note that, according to hospital records, the patient was a morbidly obese ~~male~~ weighing between 450 – 500 lbs. The filter was placed in a normal sized vena cava and there were no immediate complications. ~~According to a Pathology Associates report,~~ the filter was found to be intact, and the large thrombus surrounding the filter was approximately 10 cm long X 3 cm in diameter. To date, no formal lawsuit from the family of the deceased has been filed.

The second incident took place in Grand Rapids, MI. From the information available to date, we know that the Recovery Filter was placed in a female patient for deep vein thrombosis. The filter had been placed approximately 13 days prior to death, March 31, 2004. The patient was then released from the hospital on April 6, 2004 and expired on April 13, 2004. The medical examiner's report states that the cause of death is cardiac rupture as a result of a puncture to the right ventricle by an inferior vena cava filter.

The size of the clot at the time of the autopsy was approximately 3 cm in diameter by 50 cm in length. There were no design or manufacturing defects found to be associated with the filter. The BPV Product Assessment Team has concluded that the Recovery Filter captured a large embolic load with resulting increase in venous pressure that lead to inferior vena cava dilation greater than 28 mm resulting in migration. Final autopsy report will be available during the week of May 4.

The attached pages provide recommendations and critical information relating to the following components of your crisis communications program:

- I. Re-distributing Bard's Communications Policy
- II. Media Monitoring
- III. Message Approval
- IV. Establishing A Core Response Team
- V. Audience Outreach Team
- VI. Top Media Interview Dos and Don'ts
- VII. External Allies/Experts
- VIII. Key Studies
- IX. News Breakdown
- X. Newsmaker's Bill of Rights
- XI. Proactive Media Outreach
- XII. Step-by Step Management of Most Likely Scenarios:
- XIII. H&K Team Contact Information
- Addendum:
  - A. Key Messages – Recovery Vena Cava Filter: General Messages
  - B. Key Messages for Specific Incidents:
    - Specific to Miami Incident
    - Specific to Grand Rapids, MI Incident
    - Specific to Both Incidents
  - C. Draft General Letter-To-The-Editor
  - D. Draft Miami Letter-To-The-Editor
  - E. Draft Miami Letter-To-The-Editor
  - F. Media Lists
  - G. Recent Sample Article: Bariatric Surgery in General

I. Re-distributing Bard's Communications Policy

To prevent any Bard employee from speaking with members of the media, it would be wise to redistribute Bard's communications policy company-wide twice each year beginning with 2Q 2004. If Bard is notified that a lawsuit has been filed, dissemination of the communications policy *again* specifically to the Bard Peripheral Vascular Division as well as C.R. Bard Corporate employees, should be considered.

Anyone who may be most likely to receive phone calls from members of the media (e.g., administrative staff for corporate executives and field sales representatives who sell vena cava filters) must have copies of the communications policy and should be required to sign a confirmation form that they have read and understand these guidelines.

All Bard employees must know to direct any media inquiries directly to Holly Glass. With the communications guidelines redistributed several times each year, employees will have this information top-of-mind.

II. Media Monitoring

H&K has begun monitoring regularly for any print, broadcast and online news coverage related to the company or the Recovery Vena Cava Filter. To do this effectively, H&K is using the Factiva database, Google News and Video Monitoring Services (VMS). Particular emphasis is placed on news generated from the following markets: greater New York City (Bard Corporate HQ); Tempe, Arizona (Bard Peripheral Vascular HQ); Miami, Florida (location of case under investigation) and Grand Rapids, Michigan (location of case under investigation).

We are searching for the following terms.

- C.R. Bard
- Bard Peripheral Vascular
- Recovery Vena Cava Filter
- Vena cava filter
- Pulmonary embolism
- Baptist Hospital (Miami, FL)
- Miami Cardiac & Vascular Institute (MCVI)[NA1]
- [NAME OF LAW FIRM FILING SUIT IF SUIT IS FILED]
- Any filter mentions in Grand Rapids, MI

III. Message Approval

Key messages (see appendix; still to be reviewed and finalized) serve as the foundation for responding during any media interviews that may arise as a result of the pending investigations. It is critical that this messaging be updated as new details arise.

The approved messaging will be incorporated into external materials that will be distributed to Bard's sales force, customers, physicians, employees, suppliers and others, as needed. Bard is then prepared to handle any media inquiries. Furthermore, H&K's on-camera Q&A Training will help prepare spokespeople for any local or trade press inquiries that are posed; additional "on-the-spot" training and messaging discussions should be considered prior to responding to national top-tier press inquiries.

IV. Establishing A Recovery Core Vena Cava Filter Response Team

The following Bard and H&K employees should comprise the Core Response Team (CRT) for the Recovery Vena Cava Filter product. These individuals will receive notification when a press inquiry is received or when a negative article requiring action appears. This group will convene within several hours to approve response strategy, review specific messaging and determine next steps.

Core Response Team:	Phone Numbers:	E-mail Address:
Holly Glass	Office-703-754-2848 Cell-571-243-1952 Home-571-261-1425	holly.glass@crbard.com
Janet Hudnall	Office-480-303-2630 Cell-602-881-1331	janet.hudnall@crbard.com
Donna Passero	Office-908-277-8335 Cell-908-803-9346 Home-973-394-0052	donna.passero@crbard.com
Chris Ganser	Office-908-277-9338 Cell-908-568-9411 Fax-908-277-8087	christopher.ganser@crbard.com
Doug Uelmen	Office-480-303-2629 Cell-TBD Home-TBD	doug.uelmen@crbard.com
John McDermott	Office: 480-303-2673 Cell: 602-684-7309	john.mcdermott@crbard.com
Rob Carr	Office: 480-303-2684 Cell: 480-220-2322	robert.carr@crbard.com
Brian Berry	Office: Cell:	brian.berry@crbard.com
Adjunct – John Lehmann, MD	Office-617-489-7080 Cell-508-341-8942 Home-508-358-5365	jlehmann@lehmannthomas.com
Frank Mankewicz	Office-202-944-5141 Cell-202-258-9020 Home-202-462-7202	fmankiewicz@hillandknowlton.com
Lee Lynch	Office-202-944-5186 Cell-571-214-8799	llynch@hillandknowlton.com
Kimberly Ocampo	Office-202-944-1905 Cell-202-997-4420	kocampo@hillandknowlton.com

CRT Conference Calls
The following telephone line is available 24 hours a day, seven days a week for the CRT to use for conference calls.

- Toll Free Dial-In Number: 1-888-453-5732
- Participant Passcode: 500965

V. Recovery Vena Cava Filter Audience Outreach Team

Depending on the situation, the CRT may determine that there is a critical need to contact other key audiences outside of this immediate response group. To facilitate effective and efficient communications among the various company divisions and appropriate external audiences, a point-of-contact has been designated to conduct this outreach. They are:

Audience Outreach Team:	Phone Numbers:	E-mail Address:
Additional Media: Holly Glass	Office-703-754-2848 Cell-571-243-1952 Home-571-261-1425	holly.glass@crbard.com
CEO and Board of Directors: Holly Glass	Office-703-754-2848 Cell-571-243-1952 Home-571-261-1425	holly.glass@crbard.com
Recovery Filter Field Sales Reps: Janet Hudnall Carol Stone	Janet: Office-480-303-2630 Cell-602-881-1331 Carol: Office-908-277-8301 Cell-908-507-6574 Home-908-526-5579	janet.hudnall@crbard.com carol.stone@crbard.com
Recovery Filter Physicians: Janet Hudnall	Office-480-303-2630 Cell-602-881-1331	janet.hudnall@crbard.com
Customers and Field Reps: Janet Hudnall	Office-480-303-2630 Cell-602-881-1331	janet.hudnall@crbard.com
All Other Employees: Diana McHugh	Office-908-277-8191 Cell-908-571-2841 Home-908-835-0107	diana.mchugh@crbard.com
Suppliers/Operations: Frank Maloit	Office-908-277-8177 Cell-908-528-3537 Home-610-330-9082 Home-781-837-9530	frank.maloit@crbard.com
Shareholders and Wall Street: Eric Shick	Office-908-277-8413 Cell-908-256-4238 Office- 908-277-8265	eric.shick@crbard.com

VI. Top Media Interview Dos and Don'ts

Following is a list of general dos and don'ts for interviews with major top media outlets.

Dos

- Offer a physician spokesperson for comment.
- Offer a researcher, patient or corporate executive for further insight.
- Offer medical studies validating Recovery Vena Cava Filters or retrievable vena cava filters in general.
- Ask for a list of questions, parameters of the story and permission to record your own video of the interview or any interviews with Bard employees, patients or physicians.
- Offer video of Bard's headquarters, if you already have a tape available.
- Manage the story. Draw the line at non-company spokespersons, "trial witnesses", salespersons, product designers, etc.
- Stay focused on the success rate and clinical effectiveness of the products, rather than the claims. Stick to your key messages.
- Include day-before and day-of key audience notification in your communications strategy. Assume key audiences such as employees, physicians, shareholders, customers and field sales reps will see the story. Be prepared to notify them about when the segment will air or has just aired, and provide a clear, convincing cover letter with your key messages, as well as a breakdown of comments made in the story matched with corresponding facts.

Don'ts

- Play favorites with the members of the media.
- Answer a question with "No Comment."
- Don't try to minimize the problem.
- Don't release sensitive or proprietary information.

VII. External Allies/Experts

Physician Spokespeople
If a reporter calls for comment, Bard should have reputable physicians confirmed to participate in interviews to attest to the product's success rate and the value it provides to patients.

The below physician has been identified to serve as a spokesperson who can speak to the value of the filter.

Gary S. Cohen, MD
Chief, Interventional Radiology
Temple University Medical Center
3401 N. Broad St.
Philadelphia, PA 19140
(215) 707-3951
cohenator@aol.com

Third Party Industry Organizations and Potential Allies
Board members and other prominent leaders from ally organizations may be able to lend their credibility to Bard by providing ally spokespersons who can speak to the value of the retrievable Recovery Vena Cava Filter products (or retrievable vena cava filters in general) and Bard's position as a leader both in terms of innovation and customer care/safety. Allies may include representatives from the following organizations:

- Society of Interventional Radiology
- Association for the Advancement of Medical Instrumentation
- Medical Device Manufacturers Association
- Society for Vascular Surgeons

We currently are researching whether these organizations would be willing to speak to the media if an inquiry arises. For regional or local media outlets, it may be necessary to provide local sources. As the scenario develops, we may work with other third-party associations to determine local spokespeople.

In addition, Bard may want to consider either securing the partnership of a general medical device or consumer organization that can speak broadly about the value of Bard's products for consumers, such as:

- The Medical Device Manufacturers Association
- Center for Consumer Affairs or
- American Council on Consumer Interests (ACCI)

Finally, another consideration is for Bard to create a third-party organization that focuses on the enormous benefit of medical progress for consumers to override the negative perceptions created through a few (often frivolous) lawsuits.

VIII. Key Studies

Two studies are available specific to the Recovery Filter.

The Recovery Filter has been used in Canada by a single investigator and two colleagues at six Toronto area hospitals in 58 subjects, under the Special Access regulations. Although essentially only one physician used the device, removal was performed by three physicians with different support staff and imaging equipment.

Of the 58 filters implanted, a total of 46 have been retrieved, 8 remain in place, and 4 [NA2]patients have died with filters in place of causes unrelated to filter placement or retrieval (leukemia, cancer, polyarteritis and pulmonary aspergillosis, and hemorrhagic stroke). Time to removal ranged from 1 to 161 days, average 60 days.

In addition, the Recovery Filter underwent testing (bench top or animal studies or a combination of both) according to FDA guidelines to obtain FDA concurrence.

[NEED ABSTRACTS FOR THE ABOVE AND ADDITIONAL HUMAN STUDIES]

Summaries of key medical studies highlighting the success rate of Bard's Recovery Vena Cava Filter products and other vena cava filters can be found in the appendix. We have produced three separate sections of summarized studies: one focuses on the success of (permanent) [NA3]vena cava filters in general; the second focuses on retrievable vena cava filters as a whole; and the third details studies on Bard's Recovery Vena Cava Filter specifically. These summaries will serve as handouts and references for the media.

IX. News Breakdown

There are many various forms a news story can take and often one precedes another. To understand how news stories are originally generated and often end up featured on weekly news magazine shows, an explanation of how the media generally works is provided below. Please note there are always exceptions to the standards.

Wires – Associated Press, Bloomberg, Dow Jones, Reuters
National Dailies – *USA Today, New York Times, Wall Street Journal*
Top Market Dailies – *Los Angeles Times, Boston Globe, Washington Post*
Trades – *The Gray Sheet, MDDI, Medical Device Litigation Reporter*
News Magazine – *U.S. News & World Report, Time, Newsweek*
Daily News Program – Dateline, World News Tonight
Weekly News Program – 60 Minutes, 60 Minutes II, 48 Hours Investigates, 20/20